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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/508,527 07/17/00 ITAI

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007055
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HM12/1003

EXAMINER

KIM, Y

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/508,527

Examiner

Young J. Kim

Applicant(s)

ITAI, AKIKO

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 8.

- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Information Disclosure Statement

The reference of Branden et al., Introduction to Protein Structure, pages 11, 12, 21, 22, 249 (1992), cited in the IDS received on July 17, 2000 (Paper No. 4), has not been considered because no translation has been provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are indefinite for failing to recite a final process step which agrees back with the preamble. While minor details are not required in method/process claims, at least the basic steps must be recited in a positive, active fashion. See *Ex parte Elrich*, 3 USPQ2d, p. 1011 (Bd. Pat App. Int. 1986). For example, Claims 1-10 are drawn to a method of predicting a scaffold of

a protein, yet the claims recite a final step choosing at least one template protein among the reference proteins. The claims do not set forth the conditions/state when the method has been completed [i.e., NEEDS TO AGREE WITH PREAMBLE].

Claims 1-10 are indefinite for the recitation of the phrase, "whose three-dimensional structure is known or predictable," because it becomes unclear when the structure is known and to whom the structures are known. Amending the claims recite, whose three-dimensional structure is predetermined, would overcome this rejection.

Claim 1-10 are indefinite for the recitation of the phrase, "environmental information on each amino acid residue," because it is ambiguous whether the phrase means that the environmental information is "physically on the residue," or the information is of the amino acid residues. Amending the phrase to recite, "environmental information of each amino acid residue," would overcome this rejection.

Claims 1-10 are indefinite for the recitation of the phrase, "choosing at least one template protein among the reference proteins," because it is unclear when the template protein is a reference protein or a separate protein in the pool of the reference proteins. For the purpose of prosecution, the phrase is assumed to read on the phrase, "choosing at least one protein as a template protein from the reference proteins."

Claim 2 is indefinite because it is unclear what criteria is applied when the reference protein is divided into two or more segment sequences based on the three-dimensional structure of the reference protein. It is unclear what is meant by the phrase, "based on the three-dimensional structure of the reference protein."

Claim 3 is indefinite for the recitation of the phrase, "core segment sequences which substantially participate in the formation," because it is vague and indefinite when a segment sequence "completely participate" or "substantially participate." The requisite degree is not defined in the specification, rendering the claims vague and indefinite.

Claim 4 is indefinite for the recitation of the phrase, "matching is conducted based on the information on the degree of burial into the inside of the protein" because it is not set forth what is being buried into the inside of the protein.

Claim 7 is indefinite for because the sub-step (b) is redundant of sub-step (a). Sub-step (a) already requires the limitation "optionally considering gaps at one end or both ends," thus consideration of more than one gap.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Database is considered a non-statutory subject matter because the database itself, does not produce a "useful, concrete and tangible result." Database itself does not extend the capability of the computer, which comprise a computer readable media, to operate in a different way, i.e., extend its operation. A software on a computer readable media (a functional descriptive material), for example, would be statutory subject matter because its installation would extend the computer's capability to operate, producing useful results whether they be

"number crunching, outputting numbers, etc. A database, however, is analogous to a music CD ROM, a nonfunctional descriptive material (MPEP 2106), a non-statutory subject matter. CD ROM containing music is certainly on a computer readable media. It, however, is a non-statutory subject matter because its installation into the computer does not produce a "useful, concrete and tangible result" which extend the computer's capability. MPEP 2106-1(b) states that:

"Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101... Where certain types of descriptive material, such as music, literature, art photographs and mere arrangements or compilations of facts or data [thus a database], are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer" [comment added].

Since database is a mere collection and/or arrangement of data on a computer-readable media, and it does not extend the computer's capability to produce a useful result, it is considered non-statutory subject matter.

Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make a claim statutory (MPEP 2106(1)). Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101 (MPEP 2106(b)).

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the

stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents (See also MPEP 2106(b)).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8, 10, and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by

Bystroff et al. (Journal of Molecular Biology, 1998, vol. 281, pages 565-577).

Claims 1-8 and 10 are drawn to a method of predicting a structure of a query protein via using a three-dimensional database and comparison of segments of the query protein to that of the proteins of known structure in the database. Embodiments are drawn to the iteration of the actual comparison procedures (i.e., packing, or hydrophobic or hydrophilic).

Claim 11 is drawn to a three dimensional database comprising environmental information.

Bystroff et al. discloses a computerized method of predicting local structure in proteins using a library of sequence-structure motifs (or three dimensional databases) (Abstract, pp. 574). The database is disclosed as having information regarding type-II β -turn, a frayed helix, a proline-terminated helix, backbone torsion angles (or environment information) (Abstract). The

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reference also discloses that the method employs segmentation analysis comprising eight residue segments (bottom paragraph, 1st column, pp. 566). The prediction method also involves confidence scoring (1st column, pp. 567).

The actual iteration of comparison steps is not explicitly disclosed but it is considered that an ordinarily skilled artisan is knowledgeable of such steps.

Therefore Bystroff et al. anticipates the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bystroff et al. as applied to claim 1-8 and 11 above, and further in view of Luthy et al. (Nature, 1992, vol. 356, pages 83-85 IDS #7, paper no. 4).

Bystroff et al. do not disclose the method further comprising the step of normalizing the scores by using a self matching score.

Luthy et al. disclose a method of self matching normalization (Abstract and entire reference).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Bystroff et al. and Luthy et al. to arrive at the invention as claimed because by doing so, the ordinarily skilled artisan would have been able to confirm the

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predicted structure produced by the method of Bystroff et al. by the teachings Luthy et al. One of ordinary skill in the art would have been motivated with the motivation given by Luthy et al. wherein they disclose that, "the challenge (verifying that final predicted protein structure is correct) is to distinguish between a mistraced or wrongly folded model, and one that is basically correct," and disclose that their teaching, is an effective test of the accuracy of a 3D protein model, comparing the model to its own amino-acid sequence (self matching) (Abstract and Figure 1).

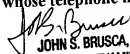
Therefore, the invention as claimed is obvious over the cited references.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)).

NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JOHN S. BRUSCA, PH.D.
PRIMARY EXAMINER

Young J. Kim

09/28/01 